

**REMARKS/ARGUMENTS**

The Examiner's attention to the present application is noted with appreciation. The claims are amended consonant with the Examiner's suggestions in paragraphs numbered 3, 5 and 6.

**Claims Rejections 35 U.S.C. § 112**

*Claims 1, 4-13, and 15 rejected under 35 U.S.C. § 112, second paragraph -- Office Action paragraph numbered 5.* Claims 1, 4 and 5 are amended as suggested, with a "wherein" clause.

*Claims 1, 4-13, and 15 rejected under 35 U.S.C. § 112, second paragraph -- Office Action paragraph numbered 6.* Claims 1, 5 and 15 are amended as suggested.

*Claims 1, 4-13, and 15 rejected under 35 U.S.C. § 112, first paragraph -- Office Action paragraph numbered 8.* This ground of rejection is respectfully traversed. Use of statistical methods, including "statistically relevant samples," is well known in the biological arts. The specification clearly discloses use of statistical methodologies. See, e.g., Example 14, page 12, lines 34-37, discussing that there were statistically significant differences in reactivation rates in the described experiment. See *also* page 7, lines 32-35, discussing the need in some models to have higher quantities of HSV in order to have "a statistically desirable and significant rate of central nervous system injury."

*Claims 1, 4-13, and 15 rejected under 35 U.S.C. § 112, first paragraph -- Office Action paragraph numbered 11.* In response to the Office Action, claims 1 and 5 are amended to provide that it is a statistically significant number of mice which is "two or more mice." It is noted that claim 4 contains the limitation "two or more."

*Claims 5, 6, 8, 10, 11 and 15 rejected under 35 U.S.C. § 112, first paragraph -- Office Action paragraph numbered 13.* In response to the Office Action, claim 5 is amended to include a "correlating reactivation by comparison" step h). As amended, it is submitted that the objection is fully addressed.

**Claims Rejections 35 U.S.C. § 103**

*Claims 1, 4 and 6-13 rejected under 35 U.S.C. § 103 as being unpatentable over the teachings of Norval et al. in view of Wright and further in view of Spruance et al. and Rooney et al.* Applicant respectfully traverses this ground of rejection. Initially, Applicant notes that no less than four separate references are combined for this obviousness rejection. The Office Action asserts that Norval et al. discloses that reactivation "occurred in mice not exposed pre-infection to UV that were not tape stripped..." The Office Action further recognizes that while the reactivation in the mice not pre-exposed was less than that of the mice that were, "the reference nonetheless indicates that exposure to UV prior to infection is not a requirement for infection reactivation." However, the rejection is based on a combination of references. That combination does not result in the claimed invention. Why? Because Norval et al. specifically discloses and states a hypothesis that negates the combination. The Norval et al. reference specifically developed the "hypothesis ... that u.v.-irradiation before primary infection with HSV induces a suppressive immune response to the virus which affects the virus-host interaction and accounts for a high incidence of recrudescence lesion on subsequent stimulus." (Abstract, *J. Gen. Virol.* 68: 2693, emphasis added.) This teaching was adopted and reinforced by Spruance, who in discussing the Norval et al. reference, state that a murine model in which UV exposure 3 days prior to primary infection "was postulated to induce a suppressive immune response and to alter the virus-host interaction." Thus Norval et al., both independently and as interpreted by Spruance, stand for the proposition that UV exposure prior to primary infection is desirable in any model system. This directly contradicts the teaching of Applicant, and teaches away from Applicant's invention.

In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983); see generally MPEP § 2141.02. As the Federal Circuit in *Norton* stated, with respect to a mechanical invention, “[b]ecause that insight was contrary to the understandings and expectations of the art, the structure effectuating it would not have been obvious to those skilled in the art.” 713 F.2d at 785 (citations omitted). The same rule applies here. Both *Norval et al.* and *Spruance* contain “understandings and expectations” contrary to Applicant’s invention, and thus cannot properly be applied in an obviousness rejection under section 103.

In applying section 103, the combinations must be assessed “as a whole.” In discussing this standard, the Federal Circuit has stated:

Section 103 precludes this hindsight discounting of the value of new combinations by requiring assessment of the invention as a whole. This court has provided further assurance of an “as a whole” assessment of the invention under § 103 by requiring a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner. In other words, the examiner or court must show some suggestion or motivation, before the invention itself, to make the new combination.

*Ruiz v. A.B. Chance Company*, 357 F.3d 1270, 1275 (Fed. Cir. 2004). Given the express teaching of *Norval*, an artisan of ordinary skill would not combine one isolated description of data with the other cited references, given the express teachings of *Norval* and those that followed. There is, simply put, no “suggestion or motivation” to combine the cited references to arrive at the claimed invention.

*Claims 5 and 15 rejected under 35 U.S.C. § 103 as being unpatentable over the teachings of Norval et al, Wright, Spruance et al. and Rooney et al, further in view of the teachings of Rooney II (Lancet).* Applicant respectfully traverses this ground of rejection. *Rooney II (Lancet)* is cited for the proposition that a sunblocking agent may prevent UV-light induced reactivation of recurrent HSV. However, as discussed above the remainder of the references, either alone or in combination, do not suggest or

make obvious Applicant's invention as set forth in claims 5 and 15. Specifically, Norval et al. and Spruance both explicitly adopt and teach the hypothesis that UV radiation prior to primary infection is desirable. Accordingly, the combination of Rooney II with the other cited art does not render Applicant's invention obvious.

### Conclusion

In view of the above amendments and remarks, it is respectfully submitted that all grounds of rejection and objection have been avoided and/or traversed. It is believed that the case is now in condition for allowance and same is respectfully requested.

If any issues remain, or if the Examiner believes that prosecution of this application might be expedited by discussion of the issues, the Examiner is cordially invited to telephone the undersigned attorney for Applicant at the telephone number listed below.

Respectfully submitted,

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